### **REMARKS**

The Office Action mailed January 7, 2009 has been received and reviewed. All claims stand rejected. The claims are to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Support for the amendments to claims 1, 8, and 20 may be found throughout the Specification and, for example, at page 4, lines 7-25 of the published application. No new matter has been presented. Reconsideration is respectfully requested.

# A. 35 U.S.C. § 112, second paragraph

Claim 20 is rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse the rejection.

The Office alleges that "the claim does not set forth any steps involved in the method/process [and that] it is unclear what method/process applicant is intending to encompass." *Office Action* sent January 7, 2009, page 3. Appropriate corrections have been made.

Therefore, applicants respectfully request the withdrawal of the 35 U.S.C. § 112, 2<sup>nd</sup> paragraph rejection.

#### B. 35 U.S.C. § 101

Claim 20 is rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process. *Office Action* sent January 7, 2009, page 3. Appropriate corrections have been made. Therefore, applicants respectfully request the withdrawal of the 35 U.S.C. § 101 rejection.

### C. 35 U.S.C. § 102(b)

Claims 1-5, 11-12, and 20 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by U.S. Patent 5,189,053 to Willis et al. ("Willis"). Applicants respectfully traverse the rejection.

Unless a single prior art reference describes "all of the limitations claimed" and "all of the limitations [are] arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN Inc. v. VeriSign Inc.*, No. 07-1565, slip op. at 17-18 (Fed. Cir. Oct. 20, 2008). A single prior art reference must "clearly and unequivocally" describe the claimed invention "without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *Id.* at 19 (citing *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)).

Amended claim 1 is not anticipated by Willis because Willis does not describe each and every element of claim 1. Willis does not describe the element of "deterring ticks from infesting the animal." Instead, Willis describes using the compounds of Formula I in order to combat active tick infestations. Willis, at col. 3, lines 1-3, col. 28, lines 28-56. The examples of Willis merely show that the compound of Formula I may be used to kill ticks. In Example 2A, Willis measures the mortality rate of ticks after exposing them to the compounds of Formula I. In Example 2B, Willis injects the compounds of Formula I into female ticks in order to measure mortality. However, Willis never considers the deterring effect of the compounds of Formula I before infestation occurs. For instance, Willis does not measure the number of alive, unattached, and unengorged ticks and, therefore, does not describe "deterring ticks from infesting the animal." The Specification describes that "deterrents have the task of deterring harmful or troublesome arthropods from contacting, stinging or feeding on areas that are attractive to them" and that "[t]he deterrent...effect after administration of the compound results in anti-attachment and anti-feeding of the parasites." Willis tests the compounds of Formula I only after infestation already occurred and does not consider any deterrent effects. Dependent claims 2-5 and 11-12 and independent claim 20 are novel for at least the same reasons as is claim 1.

Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. §102(b) rejection of the claims.

### D. 35 U.S.C. § 103

Claims 1-10 and 13-19 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent 5,189,053 to Willis. Applicants respectfully traverse this rejection.

A framework for applying the statutory language of §103 is set out in *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966):

"Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or not obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."

#### *Id.*, at 17–18.

To establish a prima facie case of obviousness, the prior art itself or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention are to have taught or suggested the claim elements. Additionally, there must have been "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 USPQ2d 1385 (2007). "Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed...To facilitate review, this analysis should be made explicit." Id. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Furthermore, to establish a prima facie case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. KSR, 127 82 USPO2d at 1385.

Even if a prima facie case for obviousness is established by the Examiner, which

applicants dispute in this case, *Graham* set forth a broad inquiry and invited those making decisions as to patentability, where appropriate, to look at any secondary considerations that would prove instructive. *Id.* Secondary considerations include unexpected results.

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."

Id. at 1389.

"A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See Graham, 383 U.S. at 36 (warning against a 'temptation to read into the prior art the teachings of the invention in issue' and instructing courts to 'guard against slipping into the use of hindsight'" (quoting Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co., 332 F. 2d 406, 412 (CA6 1964)))." Id. at 1397.

Claim 1 is not obvious because Willis and the level of ordinary skill do not teach or suggest each and every element of the claim. Willis does not describe the element of "deterring ticks from infesting the animal." Instead, as previously discussed in the anticipation rejection of claim 1, Willis teaches use of the compounds of Formula I to combat active tick infestations. *Willis*, at col. 3, lines 1-3 and col. 28, lines 28-56. Claims 2-10 and 13-19 are not obvious for at least the same reasons as is claim 1.

Claim 6 is further allowable because Willis and the level of ordinary skill do not teach or suggest the element of "wherein the animal is a dog or cat." The Office suggests that it would have been *prima facie* obvious to apply the compound of Formula I in Willis to any animal including dogs and cats with a reasonable expectation of success. *Office Action* sent January 7, 2009, page 6. However, Willis does not even mention administering the compound of Formula I to any animal but mice. *Willis*, Example 7A. Even then, Willis does not administer the

compounds to combat a tick infestation, let alone deter ticks from infesting the animal. Instead, Willis administers the compound to mice in response to an infestation by an endoparasite (murine gastrointestinal nematode *Heligmosomoides polygyrus*). A person of skill in the art would have no expectation of success in administering the compounds of Formula I to a dog or a cat to deter an ectoparasitic tick infestation when Willis merely teaches administration to mice in order to combat an already proceeding endoparasitic infestation. Additionally, Willis does not teach that these toxic compounds are safe for administration to a dog or a cat. A person of skill in the art would recognize that mortality rates and long or short term toxicity effects of pet dogs and cats play an important role in providing a method for deterring tick infestations. No expectation of success exists where the compounds are merely administered to mice without attention to the host's safety. Claims 10, 13, 15, 17, and 18 are not obvious for substantially the same reasons as is claim 6.

Claims 7, 8, 14, and 16 are not obvious because Willis does not teach or suggest an initial dosage of 4 mg/kg bodyweight of the animal followed by weekly administration of doses of 2 mg/kg bodyweight of the animal. Instead, Willis administers a dosage of 100 mg/kg of bodyweight of the animal in order to kill an endoparasite. However, the compounds of claims 7, 8, 14, and 16 are used at much lower dosages to deter infestation of an ectoparasite. The Office argues that it would have been prima facie obvious to one of ordinary skill in the art...to optimize dosage of the compound for each animal based on the severity of the infestation. Office Action sent January 7, 2009, page 6. However, Willis provides no guidance regarding the dosage requirement for deterring a tick infestation. As such, Willis does not teach a value that may be "optimized" since Willis neither attempts to deter infestations, let alone tick infestations. The 100 mg/kg dosage that Willis teaches (for killing an endoparasite) is substantially different than the dosage recited by claims 7, 8, 14, and 16, namely an initial 4 mg/kg of bodyweight administration followed by a weekly 2 mg/kg of bodyweight administration. A person of skill in the art could not predictably arrive at the low dosage recited by claims 7, 8, 14, and 16 after considering the teachings of Willis which include a dosage that is 25 times higher, has only a 50% kill efficiency, and kills a different type of insect without any deterrence measured. Additionally, the Office suggests that the dosage could be optimized based on the amount of

infestation. Claims 7, 8, 14, and 16, however, recite, "[a] method for deterring ticks." As such, prior infestation is not a requirement of the claims and without infestation, there is no need to administer any compounds to the animal. After considering the teachings of Willis, a person of skill in the art would not consider administering the compounds of Formula I to the animal if no infestation is present. Therefore, no need exists to "optimize" the dosage requirement. Applicants, however, have taught that the recited dosages deter ticks from infesting an animal.

Claim 1 is further not obvious because no reason exists that would have prompted a person of ordinary skill in the relevant field to modify the prior art elements in the manner claimed. Willis teaches that the compounds of Formula I can be utilized to kill ticks. Willis does not teach that these compounds may be used to combat an ectoparasitic tick infestation on an animal. However, even if Willis did teach that an ectoparasitic tick infestation on an animal could be combated, which it does not, it would not lead a person of skill in the art to the invention encompassed by claim 1, reciting "a method for deterring ticks." The compounds of claim 1 may be administered to an animal without a previous sign of infestation in order to deter ticks from infesting the animal. As such, a person of skill in the art would not administer the compound of claim 1 to an animal absent a tick infestation. It was applicants who determined that the compound of claim may be used to deter ticks from infesting the animal. The Office is using improper hindsight to arrive at the invention encompassed by claim 1.

The claims recite a new use for the compounds of Formula I <u>and</u> such use exhibits unexpected properties. While a new use for an otherwise obvious composition cannot render a claim to the composition patentable, any unexpected results accompanying a method including the new use leads to patentable subject matter. *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007). In this case, the claims recite a new use for the compounds of Formula I namely, "deterring ticks from infesting the animal." At the time of the invention, compounds of Formula I were not known to be effective in deterring ticks from infesting an animal. Willis merely teaches that the compounds of Formula I could be used to kill ticks. However, a person of skill in the art would not have predicted that these compounds could be used to deter ticks from infesting an animal. The new use of these compounds provides the unexpected result of deterring ticks from infesting an animal. Therefore, as outlined in Sullivan, their use is not

obvious.

Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 103(a) obviousness rejection of the claims.

## E. Provisional Non-statutory Obviousness-type Double Patenting Rejection

Claims 1-20 are provisionally rejected on grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 5-18 of co-pending Application No. 11/698,683. Applicants duly note the provisional rejection of claims 1-20. Applicants will address the provisional rejection upon the allowance of this application or Application No. 11/698,683, and, accordingly, request that the rejection be held in abeyance. MPEP § 714.02(b).

Claims 1-20 are provisionally rejected on grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 6-11 and 19-20 of co-pending Application No. 10/577,232. Applicants duly note the provisional rejection of claims 1-20. Applicants will address the provisional rejection upon the allowance of this application or Application No. 10/577,232, and, accordingly, request that the rejection be held in abeyance. MPEP § 714.02(b).

## **CONCLUSION**

Applicants believe the application is in condition for allowance, and a notice of allowance is kindly solicited. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

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Respectfully submitted,

Steffen Soller

Registration No. 62,497

Attorney for Applicants

TraskBritt, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

16